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EXAMINER	
SPIEGLER, ALEXANDER H	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/034,934	RECIPON ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/17/04; 5/7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. This action is in response to Applicants' response, filed on April 21, 2004. Currently, claims 1-5 and 7-9 are pending and are rejected herein. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. This action is made FINAL. Any objections and rejections not reiterated below are hereby withdrawn. Specifically, 112, 2nd paragraph over "selectively hybridizes" has been withdrawn in view of Applicants' amendment.

Specification

2. Claims 1-5 and 7-9 are objected to because the claims recite non-elected subject matter. Applicants should amend the Claims to recite only the elected sequence, SEQ ID NO: 8.

Appropriate correction is required.

Applicants Arguments

Applicants amended the claims to recite SEQ ID NO: 8, however, Claim 1 also recites SEQ ID NO: 7. Applicants' argue SEQ ID NO: 7 is "related" to SEQ ID NO: 8, and "the relationship of SEQ ID NO: 7 and 8 is clear from the sequence listing". See Applicants' response on page 5.

Response to Applicants Arguments

Claims 1-5 and 7-9 remain objected to for several reasons. First, it is not clear how SEQ ID NOS: 7 and 8 are "related", this "relationship" is not clear from the sequence listing (absent any discussion by Applicants as to how they are related), and this "relationship" was not previously disclosed in Applicants' response of September 2, 2003. Furthermore, SEQ ID NO: 7

was not examined in the previous office action. See 37 CFR 1.142(b) and MPEP § 821.03. Accordingly, SEQ ID NO: 7 has not been examined on the merits.

Information Disclosure Statement

3. The information disclosure statements filed on March 17, 2004 and May 7, 2004 comply with CFR 1.97, 1.98, and M.P.E.P. 609, and have been considered (see enclosed, signed PTO-1449).

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS

Claim Rejections - 35 USC § 112

Indefiniteness

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-5 and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 and 7-9 are indefinite over "lung cancer specific" because it is not clear as to whether this nucleic acid is only found in lung cancer samples, is expressed only in lung cancer samples, or could be found or expressed in other samples, such as samples that are not lung cancer samples. It is also not clear if this recitation is only "lung cancer specific" in humans or whether it can be specific in other animals as well. Furthermore, the specification does not specifically define this recitation.

Written Description

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5 and 7-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1-5 and 7-9 are directed to nucleic acids that selectively hybridize under stringent conditions to the nucleic acid of SEQ ID NO: 8, and nucleic acids having at least 85% sequence identity to SEQ ID NO: 8. Claims reciting nucleic acids having at least 85% sequence identity to SEQ ID NO: 8, and nucleic acids that selectively hybridize under stringent conditions to the nucleic acid of SEQ ID NO: 8 are inclusive of sequences from other species, mutated sequences, and allelic variants having different functional activities than that of the nucleic acid (SEQ ID NO: 8) encoding the polypeptide of SEQ ID NO: 87. These claims include a large genus of nucleic acids encoding polypeptides, having unique functional activities, whereas applicants only disclose one member of the genus (i.e., SEQ ID NO: 8).

In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, only one member (SEQ ID NO: 8) has been defined by its structure. It is then determined whether a representative number of species have been

sufficiently described by other relevant identifying characteristics (e.g., restriction map, chromosomal map position, biological activity of an encoded protein, etc.). In the instant case, no such identifying characteristics have been provided for ant of the nucleic acids.

In *The Reagents of the University of California v. Eli Lilly and Co.,* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention". In the instant case, the claims are drawn to generic statements, which define a genus of nucleic acids by only their functional activity; however, the specification does not provide an adequate written description of this genus.

While at the time filing Applicants were in possession of SEQ ID NO: 8, the specification does not support the broadly claimed genus. Accordingly, the claimed invention lacks an adequate written description.

Applicants Arguments

Applicants argue pages 13-16 and Example 1 teach methods for ascertaining sequences that meet the structural and functional limitations of the claimed nucleic acids. See Applicants' response on page 7. Applicants also argue methods for assessing percent identity and/or the

ability of a nucleic acid sequence to hybridize under stringent conditions is performed routinely in the art. See Applicants' response on page 7. Furthermore, Applicants argue there is clear possession of additional nucleic acid sequences based on the disclosure of SEQ ID NO: 8. See Applicants' response on page 7.

Response to Applicants Arguments

Applicants' arguments have been considered, but are not persuasive for several reasons. First, while pages 13-16 and Example 1 teach general concepts relating to sequence identity, sequence similarity and hybridization parameters, these passages do not demonstrate that Applicants were in *possession* of the genus of nucleic acids encompassed by the claims. Furthermore, the assertion that a skilled artisan performs some methods routinely does not mean that Applicants were in possession of the claimed nucleic acids. Except for the description of SEQ ID NO: 8, Applicants have not provided an adequate written description to support the broadly claimed genus of nucleic acids. Finally, it is not clear how the disclosure of SEQ ID NO: 8 and its alleged expression in lung cancer tissues, demonstrates that Applicants were "clearly" in possession of additional nucleic acids. There is no evidence in the record to support Applicants assertions that given the disclosure of SEQ ID NO: 8, Applicants were "clearly" in possession of additional nucleic acids encompassed by the claims. Accordingly, the rejection is maintained.

Enablement

8. Claims 1-5 and 7-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described

in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support determination that a disclosure does not satisfy the enablement requirements and whether any necessary experimentation is undue (see *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). These factors include, but are not limited to:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.* at 1404.

In the instant case, the specification does not enable one of skill in the art to make and use the claimed invention for the following reasons:

(1) ***Nature of the Invention & Breadth of the Claims***

The claims are drawn to isolated "lung cancer specific" nucleic acid molecules comprising SEQ ID NO: 8, a nucleic acid sequence that encodes SEQ ID NO: 87, nucleic acid sequences that selectively hybridize under stringent conditions to SEQ ID NO: 8, and nucleic acid sequences have at least 85% sequence identity to SEQ ID NO: 8.

Thus, the claims are drawn to a large genus of possible nucleic acids. With respect to claim 1(c) and (d), the claims are drawn to that sequences from other species, mutated sequences, and allelic variants having different functional activities than that of the nucleic acid (SEQ ID NO: 8) encoding the polypeptide of SEQ ID NO: 87.

(2) ***Relative Skill of those in the Art, State of the Prior Art, Amount of Direction or Guidance Presented & Presence or Absence of Working Examples***

The specification at page 116 states that the nucleic acids of the present invention (including SEQ ID NO: 8) were procured from, and thereby known by Incyte Genomics Inc. at the time the invention was made.

Applicants allege the nucleic acids of the present invention can be used in diagnosing lung cancer (pgs. 94-100). However, Incyte nor the specification provides the skilled artisan with the appropriate guidance as to how to use the claimed nucleic acids (e.g., in diagnosing lung cancer).

Applicants teach Example 1, which teaches gene expression analysis using the data mining software CLASP™ (Candidate Lead Automatic Search Program) to analyze nucleic acids from Incyte's LIFESEQ database (pg. 116-119). Specifically, Example 1 teaches CLASP™ interrogates the LIFESEQ database to identify genes that are both specific to particular tissue types as well as differentially expressed in tissues from patients with cancer, sorts the database into tissues types, categorizes each tissue sample, and then searches for genes that are expressed in the defined tissue types and differentially in the cancer disease state.

However, the specification does not teach several elements that would be necessary to enable the skilled artisan to use the nucleic acids of the invention. For example, the specification and specifically Example 1, does not teach any expression data from the analysis relating to the claimed nucleic acids (e.g., SEQ ID NO: 8). For example, the specification does not teach a comparative readout of expression among lung tissue (if tested) versus other the expression of the claimed nucleic acids in other tissues. Furthermore, the specification does not teach what

sequences were being compared in the CLASP analysis, what tissues were involved, how many individuals were screened, what activity or function the polypeptide of SEQ ID NO: 87 has, what the statistical significance was for the CLASP 2 genes, etc.

With respect to Claim 1(c) and (d), the claims are drawn to a plurality of possible nucleotide sequence variants of SEQ ID NO: 8, wherein the specification does not provide any guidance as to how to make or alter nucleic acid sequences falling within Claim 1(c) and (d), nor does it teach how to use said sequences. Specifically, the specification is silent as to how nucleotide sequences falling within Claim 1(c) and (d) can be mutated and still have the function of encoding SEQ ID NO: 87, nor does the specification teach any variants of SEQ ID NO: 8. Furthermore, the specification does not teach the critical domains, if any, of the polypeptide encoded by the nucleotide sequences falling within Claim 1(c) and (d).

(3) ***Quantity of Experimentation Necessary & the Unpredictability of the Art***

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. In *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art.

In the instant case, the art does not teach the association/and or correlation for any of the possible nucleic acids encompassed by the claimed invention, and thus, how to use the claimed nucleic acids in, for example, a method of diagnosing lung cancer. Since it is unclear from the

teachings in the specification or the art as to how to alter the nucleotide sequences of Claim 1(c) and (d) and retain the activity of SEQ ID NO: 87, and how to use the claimed nucleic acids, absent a teaching of any expression data, or parameters for using the LIFESEQ/CLASP methodology of Example 1, it is unpredictable as to whether the claimed nucleic acids are related or associated with, or can be used in a method of diagnosing lung cancer.

In order to carry out making and using of the claimed nucleic acids, the experimentation required by the skilled artisan would be considered undue. First, the skilled artisan would have to experiment by altering any of the plurality of possible sequences encompassed by the claims to determine what sequences can be altered, and how they can be altered, and still retain the function of SEQ ID NO: 87. Additionally, once the sequences were obtained, the skilled artisan would have to test the expression of the sequences to determine whether the sequences a re specific for diagnosing lung cancer, by carrying out expression analysis studies on many samples from different tissues from both normal and diseased test subjects. Such experimentation requires a large amount of trial and error analysis, with little to no starting point, absent any teaching in the specification (see above), wherein the results of such analysis are unpredictable, and is therefore considered undue.

In essence, the experimentation that one skilled in the art would be required to perform is in fact the proposed novelty of the invention. However, "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". (*Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001).

Accordingly, in view of the unpredictability in the art and in view of the lack of specific disclosure in the specification, undue experimentation would be required to practice the invention as it is claimed.

Applicants Arguments

Applicants argue the amendment to add "lung cancer specific" clarifies the claimed nucleic acids have the functional activity of being lung cancer specific. See Applicants' response on page 8. Applicants also argue pages 13-16 and Example 1 teach methods for identifying sequences that meet the structural and functional characteristics of the claimed nucleic acids. See Applicants' response on page 9.

Response to Applicants Arguments

Applicants' arguments have been considered, but are not persuasive for several reasons. First, it is not clear what is meant or encompassed by "lung cancer specific" (see 112, 2nd paragraph rejection above). Furthermore, methods of searching for operable embodiments (or methods of searching for polynucleotides) are not equivalent to teaching how to make and use specific polynucleotides. While methods are known in the art for identifying nucleic acids, Applicants have not taught how to make and use the specifically claimed nucleic acids. In addition, Applicants have not addressed specific points raised in the rejection. The data in the specification does not adequately demonstrate the claimed nucleic acids are specifically expressed in lung cancer cells and can be used to diagnose lung cancer. Furthermore, Applicants have only provided methods that a researcher could perform to try and establish/determine how to use the claimed nucleic acids for practical purposes. However, this is not sufficient to enable the claimed nucleic acids. Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

10. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(a) as being anticipated by LIFESEQ™ Database.

The specification at page 116 states that the nucleic acids of the present invention (including SEQ ID NO: 8) were procured from, and thereby known by Incyte Genomics Inc. at the time the invention was made. Accordingly, the nucleic acids of the present invention were known and used in the art prior to the filing of the instant application.

11. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention.

The specification at page 116 states that the nucleic acids of the present invention (including SEQ ID NO: 8) were procured from, and thereby known by Incyte Genomics Inc. at the time the invention was made. Accordingly, the nucleic acids of the present invention were in public use and on sale in this country prior to the filing of the instant application.

12. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The specification at page 116 states that the nucleic acids of the present invention (including SEQ ID NO: 8) were procured from, and thereby known by Incyte Genomics Inc. at the time the invention was made. Accordingly, it appears that Applicant did not invent the claimed subject matter.

Applicants Arguments With Respect to the 102 Rejections

Applicants argue the specification does not state that the nucleic acids were procured from or known by Incyte Genomics Inc. See Applicants' response on page 10. Applicants argue they utilized their own set of algorithms referred to as CLASP™ to systematically "interrogate and analyze gene expression data in the LIFESEQ Gold database". See Applicants' response on page 10. Furthermore, Applicants argue that but for their proprietary CLASP™ algorithms, one of skill in the art would not know the claimed nucleic acids are "lung cancer specific". See Applicants' response on page 11. Applicants also argue they have amended the claims to recite "lung cancer specific" to distinguish the present invention from expression data in the LIFESEQ Gold database. See Applicants' response on page 11.

Response to Applicants Arguments

Applicants' arguments have been considered, but are not persuasive for the following reasons. First, it is not clear what is meant or encompassed by "lung cancer specific" (see 112, 2nd paragraph rejection above). Next, as taught in the specification, and again asserted in Applicants arguments, the claimed nucleic acids were contained in the LIFESEQ Gold Database and available from Incyte Genomics Inc. Despite using their own algorithms, Applicants state they "interrogate[d] and analyze[d] gene expression data *in* the LIFESEQ Gold database". That is, Applicants algorithms analyzed data (nucleic acid sequence and expression data) *from* Incyte

Genomics Inc. and determined what nucleic acids sequences were "lung cancer specific". Thus, Applicants procured the sequence information, e.g., SEQ ID NO: 8 from Incyte Genomics Inc., and therefore, Applicants did not invent SEQ ID NO: 8. Applicants seek to distinguish the data obtained from Incyte and the claimed nucleic acids by having amended the claims to recite "lung cancer specific". However, the claimed nucleic acids are still the same product, having the same structure, as the nucleic acid sequence information obtained from Incyte. The claims are drawn to products, not to methods of using the products, and therefore, absent any evidence of a structural distinction between the claimed nucleic acids and that of the nucleic acid sequences from the LIFESEQ Gold database, the claimed invention is structurally the same as the sequences in the LIFESEQ Gold database, and are therefore anticipated by LIFESEQ Gold database. Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over LIFESEQ™ Database, in view of Prendergast (USPN 5,958,753).

As discussed in the specification (pg. 116) the nucleic acids of the present invention (including SEQ ID NO: 8) were procured from, and thereby known by Incyte Genomics Inc. at the time the invention was made. The cited prior art does not teach expressing the nucleic acids using an expression system.

However, Prendergast teaches operably linking a polynucleotide into an expression vector, transforming a host cell with the resulting recombinant vectors and expressing the polypeptides encoded by the polynucleotide using the transformed host cells (see cols. 5-6, for example).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have linked the polynucleotides of the LIFESEQ Database into expression vectors, to have transformed host cells with the resulting vectors and to have used the transformed cells to express polypeptides in order to have provided an effective means for synthesizing polypeptides encoded by the isolated polynucleotides which would have allowed for the further

characterization of the functional properties of the isolated polynucleotides and the products encoded by the isolated polynucleotides.

Applicants Arguments

Applicants argue that only given the teaching of the instant specification would one of skill in the art be motivated to link the claimed nucleic acid molecules into vectors and to have expressed said vectors into host cells. See Applicants' response on page 13. Applicants also assert the claimed invention, as amended to include "lung cancer specific", distinguishes the instant invention over the prior art. See Applicants' response on page 13.

Response to Applicants Arguments

Applicants' arguments have been considered, but are not persuasive for the following reasons. First, it is not clear what is meant or encompassed by "lung cancer specific" (see 112, 2nd paragraph rejection above). Next, with respect to Applicants assertions the claimed products are different than that of the LIFESEQ Gold Database, see the above discussion under "Response to Applicants Arguments" following the 102 rejections. Furthermore, even assuming one of skill in the art would not have been motivated to have linked the claimed nucleic acids in a vector and subsequently have expressed said vector in a host cell for lung cancer specific expression, one of skill in the art would been motivated have transformed host cells with the resulting vectors and to have used the transformed cells to express polypeptides in order to have provided an effective means for synthesizing polypeptides encoded by the isolated polynucleotides, which would have allowed for the further characterization of the functional properties of the isolated polynucleotides and the products encoded by the isolated polynucleotides. Accordingly, the rejection is maintained.

Conclusion

17. No claims are allowable.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (571) 272-0747. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Alexander H. Spiegler
June 29, 2004

CARLA J. MYERS
PRIMARY EXAMINER